



To whom it may concern

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Date of issue: 23.07.2021
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Doc.-No. EIP-5014
Revision 10

Residual Solvents

ICH Q3C (R8) (EMA/CHMP/ICH/82260/2006); Ph. Eur. Chapter 5.4; USP-NF Chapter <467>; JP XVII Chapter 2.46; EMEA/CVMP/423/01-Final
MEGGLE Product: RetaLac®

The product is a co-processed, directly compressible spray agglomerate comprising 50 % Lactose Monohydrate (Ph. Eur. / USP-NF / JP) and 50 % Hypromellose (Ph. Eur. / USP-NF / JP). The monographs have undergone pharmacopoeial harmonisation.

Starting material Lactose Monohydrate (Ph. Eur. / USP-NF / JP):

Raw materials, manufacturing process and product do not contain organic solvents listed as class 1, 2, 3 solvents in the mentioned documents.

Starting material Hypromellose (Ph. Eur. / USP-NF / JP):

According to the confirmation of the supplier, organic solvents listed as class 1, 2, 3 solvents in the mentioned documents are not used in the manufacturing process. The product may contain traces of class 2 solvent methanol (i.e.: < 100 ppm).

RetaLac®:

In the manufacturing process (spray-drying of suspension), only demineralized water is used.

Organic solvents listed as Class 1, Class 2 or Class 3 solvents or any other solvents are not used.

Due to starting material Hypromellose Ph. Eur. / USP-NF / JP: As mentioned above, the only class 2 solvent likely to be present is methanol. The total amount of methanol is typically < 50 ppm and does not exceed the 3000 ppm Option 1 limit.

Best regards

MEGGLE GmbH & Co. KG


Dr. Stefan Dreiheller